# **Complete Summary**

#### **GUIDELINE TITLE**

Evidence-based guidelines for cardiovascular disease prevention in women: 2007 update.

# **BIBLIOGRAPHIC SOURCE(S)**

Mosca L, Banka CL, Benjamin EJ, Berra K, Bushnell C, Dolor RJ, Ganiats TG, Gomes AS, Gornik HL, Gracia C, Gulati M, Haan CK, Judelson DR, Keenan N, Kelepouris E, Michos ED, Newby LK, Oparil S, Ouyang P, Oz MC, Petitti D, Pinn VW, Redberg RF, Scott R, Sherif K, Smith SC Jr, Sopko G, Steinhorn RH, Stone NJ, Taubert KA, Todd BA, Urbina E, Wenger NK, Expert Panel/Writing Group, American Heart Association, American Academy of Family Physicians, American College of Obstetricians and Gynecologists, American College of Cardiology Foundation, Society of Thoracic Surgeons, American Medical Women's Association, Centers for Disease Control and Prevention, Office of Research on Women's Health, Association of Black Cardiologists, American College of Physicians, World Heart Federation, National Heart, Lung, and Blood Institute, American College of Nurse Practitioners. Evidence-based guidelines for cardiovascular disease prevention in women: 2007 update. Circulation 2007 Mar 20;115(11):1481-501. [23 references] PubMed

#### **GUIDELINE STATUS**

This is the current release of the guideline.

This guideline updates a previous version: Mosca L, Appel LJ, Benjamin EJ, Berra K, Chandra-Strobos N, Fabunmi RP, Grady D, Haan CK, Hayes SN, Judelson DR, Keenan NL, McBride P, Oparil S, Ouyang P, Oz MC, Mendelsohn ME, Pasternak RC, Pinn VW, Robertson RM, Schenck-Gustafsson K, Sila CA, Smith SC Jr, Sopko G, Taylor AL, Walsh BW, Wenger NK, Williams CL. Evidence-based guidelines for cardiovascular disease prevention in women. Circulation 2004 Feb 10;109(5):672-93.

## **COMPLETE SUMMARY CONTENT**

**SCOPE** 

METHODOLOGY - including Rating Scheme and Cost Analysis
RECOMMENDATIONS
EVIDENCE SUPPORTING THE RECOMMENDATIONS
BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS
CONTRAINDICATIONS
QUALIFYING STATEMENTS
IMPLEMENTATION OF THE GUIDELINE
INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT
CATEGORIES

#### SCOPE

## **DISEASE/CONDITION(S)**

Cardiovascular disease (CVD)

- Coronary heart disease (CHD)
- Other forms of atherosclerotic/thrombotic cardiovascular disease, such as cerebrovascular disease and peripheral arterial disease

**Note:** Acute management of vascular disease in the periprocedural or immediate posthospital settings and of valvular heart disease is covered in other American heart Association (AHA) guidelines. Management of heart failure, atrial fibrillation for stroke prevention, and cardiovascular disease (CVD) risk factors during pregnancy is beyond the scope of the present document.

#### **GUIDELINE CATEGORY**

Prevention Risk Assessment

## **CLINICAL SPECIALTY**

Cardiology
Family Practice
Internal Medicine
Nursing
Nutrition
Obstetrics and Gynecology
Preventive Medicine

## **INTENDED USERS**

Advanced Practice Nurses
Allied Health Personnel
Dietitians
Health Care Providers
Health Plans
Hospitals
Managed Care Organizations
Nurses
Patients
Physician Assistants
Physicians
Public Health Departments

# **GUIDELINE OBJECTIVE(S)**

To present the most current evidence-based clinical recommendations for the prevention of cardiovascular disease (CVD) in women  $\geq$ 20 years of age with a broad range of cardiovascular risk

#### **TARGET POPULATION**

Adult women 20 years and older with a broad range of cardiovascular risk

## INTERVENTIONS AND PRACTICES CONSIDERED

- 1. Assessment and stratification of cardiovascular risk (medical and family history, physical examination, laboratory tests, and Framingham risk assessment)
- 2. Lifestyle interventions
  - Avoidance of cigarette smoking and exposure to environmental tobacco, counseling and nicotine replacement if indicated
  - Physical activity and exercise
  - Cardiovascular or stroke rehabilitation if indicated
  - Heart-healthy diet
  - Weight maintenance/reduction through diet, exercise, and behavioral programs
  - Omega 3 fatty acid supplementation
  - Psychosocial factors (screening and treatment for depression when indicated)
- 3. Major risk factor interventions
  - Management of blood pressure through lifestyle approaches (weight management, diet, activity, moderation of alcohol) and drugs, such as thiazide diuretics
  - Management of lipids through lifestyle, diet therapy, and pharmacotherapy (low-density lipoprotein cholesterol [LDL-C]– lowering therapy (statin), niacin or fibrate)
  - Management of diabetes (glycemic control) with lifestyle and pharmacotherapy
- 4. Preventive drug interventions
  - Antiplatelet therapy (aspirin, or clopidogrel, or other antiplatelet)
  - Beta-blockers
  - Angiotensin-converting enzyme (ACE) inhibitors
  - Angiotensin-receptor blockers (ARBs)
  - Aldosterone blockade

\*Guideline developers considered but recommended against the following interventions for prevention of cardiovascular disease: hormone therapy and selective estrogen-receptor modulators (SERMs) in postmenopausal women, antioxidant supplements in general populations of women, folic acid with or without B6 and B12 supplementation, and routine use of aspirin in healthy women <65 years of age.

#### **MAJOR OUTCOMES CONSIDERED**

• Cardiovascular disease (CVD) risk, including lifetime risk and short-term absolute risk, defined by Framingham Point Score Estimates of 10-year risk

- for coronary heart disease (CHD) in women, based on age, total cholesterol, smoking status, high-density lipoprotein (HDL) levels, systolic blood pressure
- Major cardiovascular disease (CVD) clinical end points (death, myocardial infarction, stroke, revascularization procedure, congestive heart failure, or a composite cardiovascular disease end point)

#### METHODOLOGY

## METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

# DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

# **Selection of Topics and Systematic Search**

The expert panel reviewed the list of recommendations in the 2004 guidelines and suggested additional topics to be researched to determine whether they warranted discussion or a clinical recommendation. The methods for the systematic search were similar to those for the research conducted in 2003. The time period for the updated search was January 2003 through June 7, 2006. New topics were searched electronically on 3 databases from their inception (Medline, 1966 through June 7, 2006; CINAHL, 1982 through June 7, 2006; and PsychInfo, 1972 through June 7, 2006).

Briefly, studies were included if they were randomized clinical trials or large prospective cohort studies (>1000 subjects) of CVD risk-reducing interventions, meta-analyses that used a quantitative systematic review process, or surrogate end-point studies with at least 10 cases of major clinical CVD end points reported. The systematic search was conducted by the Duke Center for Clinical Health Policy Research, Durham, NC. A total of 5774 articles were initially identified; 828 were included for full-text screening, and 246 met the inclusion criteria and were included in the evidence tables. Some proposed new topics were searched but not included in the quidelines because the expert panel determined the data were insufficient to make clinical recommendations (e.g., yoga/stress reduction) or because the topic had been covered in other recent guidelines (e.g., treatment of atrial fibrillation for stroke prevention). The summary evidence used by the expert panel can be obtained online as a Data Supplement at

http://circ.ahajournals.org/cgi/content/full/CIRCULATIONAHA.107.181546/DC1.

# NUMBER OF SOURCE DOCUMENTS

246 total articles were included in the evidence tables:

Hyperlipidemia – 9 Physical activity - 11 Smoking - 1 Antiplatelet therapy – 12 Hypertension - 10 Beta-blocker therapy – 4 Cardiac rehabilitation - 3 Angiotensin-converting enzyme inhibitor (ACE)/angiotensin-receptor blockers

therapy(ARB) - 13

Weight management – 1

Diabetes mellitus - 8

Hormone replacement therapy/selective estrogen-receptor modulators (SERMs) –

Diet modification – 28

Warfarin, antiplatelet therapy, and antiarrhythmic therapy in atrial fibrillation – 27

Aspirin for primary prevention – 1 Psychosocial/depression – 10

Antioxidant supplementation – 5

Omega-3 fatty acid supplementation - 4

Folic acid supplementation, vitamin B6, vitamin B12 - 8

#### **New Search Terms**

Alcohol – 57 Congestive heart failure (CHF) rehabilitation – 3 Peripheral vascular disease (PVD) rehabilitation – 0 Yoga/stress reduction – 6 Aldosterone blocker – 4 Stroke rehabilitation – 11

# METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

#### RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

## Level of Evidence

- A. Sufficient evidence from multiple randomized trials
- B. Limited evidence from single randomized trial or other nonrandomized studies
- C. Based on expert opinion, case studies, or standard of care

#### METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses Systematic Review with Evidence Tables

# **DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE**

## **Evidence Rating and Recommendation Procedure**

A series of conference calls to discuss recommendations was conducted. Primary and secondary reviewers were assigned to each recommendation to modify any wording and to ensure that the evidence tables were complete for that topic. Each expert received a final copy of the evidence tables and voted independently on the strength of the recommendation (Class I, IIa, IIb, or III) and level of evidence (A, B, or C) (see the Rating Scheme for the Strength of the Evidence and the Rating

Scheme for the Strength of the Recommendations fields). The final rating of evidence was determined by a majority vote.

#### METHODS USED TO FORMULATE THE RECOMMENDATIONS

**Expert Consensus** 

# DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

## **Selection of Expert Panel**

The American Heart Association (AHA) Manuscript Oversight Committee commissioned the update of the guidelines and approved the chair of the expert panel, who was a nonvoting member of the panel. The leadership of each AHA scientific council and interdisciplinary working group was asked to nominate a recognized expert in cardiovascular disease (CVD) prevention who had particular knowledge about women. Major professional or government organizations with a mission consistent with CVD prevention were solicited to serve as cosponsors and were each asked to nominate 1 representative with full voting rights to serve on the expert panel. Each panel member completed a conflict-of-interest statement and was asked to abstain from discussion of or voting on any recommendations they deemed to be a potential conflict of interest. Panelists also suggested diverse professional and community organizations to endorse the final document after its approval by the AHA Science Advisory and Coordinating Committee and cosponsoring organizations.

## **Evidence Rating and Recommendation Procedure**

A series of conference calls to discuss recommendations was conducted. Primary and secondary reviewers were assigned to each recommendation to modify any wording and to ensure that the evidence tables were complete for that topic. Each expert received a final copy of the evidence tables and voted independently on the strength of the recommendation (Class I, IIa, IIb, or III) and level of evidence (A, B, or C) (see the Rating Scheme for the Strength of the Evidence and the Rating Scheme for the Strength of the Recommendations fields). The final rating of evidence was determined by a majority vote.

## **Clinical Recommendations**

Each recommendation is accompanied by the strength of recommendation and the level of evidence to support it. The strength of the recommendation is based not only on the level of evidence to support a clinical recommendation but also on other factors, such as the feasibility of conducting randomized controlled trials in women. Recommendations are grouped in the following categories: lifestyle interventions, major risk factor interventions, and preventive drug interventions.

## RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Class I: Intervention is useful and effective.

Class IIa: Weight of evidence/opinion is in favor of usefulness/efficacy.

**Class IIb**: Usefulness/efficacy is less well established by evidence/opinion.

Class III: Intervention is not useful/effective and may be harmful.

#### **COST ANALYSIS**

The guideline developers reviewed a published cost-analysis.

#### METHOD OF GUIDELINE VALIDATION

Internal Peer Review

## **DESCRIPTION OF METHOD OF GUIDELINE VALIDATION**

Modifications to text and clinical recommendations were made on the basis of peer review comments and cosponsor reviews. The guidelines were then finalized and approved by the expert panel.

This statement was approved by the American Heart Association Science Advisory and Coordinating Committee on January 9, 2007.

#### **RECOMMENDATIONS**

#### MAJOR RECOMMENDATIONS

Definitions of the strengths of the recommendations (I, IIa, IIb, III) and levels of the evidence (Levels A, B, C) are presented at the end of the "Major Recommendations" field.

# **Lifestyle Interventions**

## **Cigarette Smoking**

Women should not smoke and should avoid environmental tobacco smoke. Provide counseling, nicotine replacement, and other pharmacotherapy as indicated in conjunction with a behavioral program or formal smoking cessation program (Class I, Level B).

## Physical Activity

Women should accumulate a minimum of 30 minutes of moderate-intensity physical activity (e.g., brisk walking) on most, and preferably all, days of the week. (Class I, Level B)

Women who need to lose weight or sustain weight loss should accumulate a minimum of 60 to 90 minutes of moderate-intensity physical activity (e.g., brisk walking) on most, and preferably all, days of the week (Class I, Level C).

## Rehabilitation

A comprehensive risk-reduction regimen, such as cardiovascular or stroke rehabilitation or a physician-guided home- or community-based exercise training program, should be recommended to women with a recent acute coronary syndrome or coronary intervention, new-onset or chronic angina, recent cerebrovascular event, peripheral arterial disease (Class I, Level A), or current/prior symptoms of heart failure and a left ventricular ejection fraction (LVEF) <40% (Class I, Level B).

## **Dietary Intake**

Women should consume a diet rich in fruits and vegetables; choose whole-grain, high-fiber foods; consume fish, especially oily fish, at least twice a week; limit intake of saturated fat to <10% of energy, and if possible to <7%, cholesterol to <300 mg/d, alcohol intake to no more than 1 drink per day, and sodium intake to <2.3 g/d (approximately 1 tsp salt). Consumption of *trans*-fatty acids should be as low as possible (e.g., <1% of energy) (**Class I, Level B**).

# Weight Maintenance/Reduction

Women should maintain or lose weight through an appropriate balance of physical activity, caloric intake, and formal behavioral programs when indicated to maintain/achieve a body mass index (BMI) between 18.5 and 24.9 kg/m $^2$  and a waist circumference  $\leq$ 35 in. (Class I, Level B)

## **Omega-3 Fatty Acids**

As an adjunct to diet, omega-3 fatty-acids in capsule form (approximately 850 to 1000 mg of eicosapentaenoic acid [EPA] and docosahexaenoic acid [DHA]) may be considered in women with coronary heart disease (CHD), and higher doses (2 to 4 g) may be used for treatment of women with high triglyceride levels. (Class IIb, Level B)

## Depression

Consider screening women with CHD for depression and refer/treat when indicated (Class IIa, Level B)

## **Major Risk Factor Interventions**

# **Blood Pressure — Optimal Level and Lifestyle**

Encourage an optimal blood pressure of <120/80 mm Hg through lifestyle approaches such as weight control, increased physical activity, alcohol moderation, sodium restriction, and increased consumption of fresh fruits, vegetables, and low-fat dairy products. (Class I, Level B)

## **Blood Pressure — Pharmacotherapy**

Pharmacotherapy is indicated when blood pressure is  $\geq$ 140/90 mm Hg or an even lower blood pressure in the setting of chronic kidney disease or diabetes (>130/80 mm Hg). Thiazide diuretics should be part of the drug regimen for most

patients unless contraindicated or if there are compelling indications for other agents in specific vascular diseases. Initial treatment of high-risk women<sup>3</sup> should be with beta-blockers and/or angiotensin-converting enzyme (ACE) inhibitors/angiotensin receptor blockers (ARBs), with addition of other drugs such as thiazides as needed to achieve goal blood pressure. (Class I, Level A)

## Lipid and Lipoprotein Levels - Optimal Levels and Lifestyle

The following levels of lipids and lipoproteins in women should be encouraged through lifestyle approaches: low-density lipoprotein cholesterol (LDL-C) <100 mg/dL, high-density lipoprotein cholesterol (HDL-C) >50 mg/dL, triglycerides <150 mg/dL, and non-HDL-C (total cholesterol minus HDL cholesterol) <130 mg/dL. (Class I, Level B) If a woman is at high risk<sup>3</sup> or has hypercholesterolemia, intake of saturated fat should be <7% and cholesterol intake <200 mg/d (Class I, Level B)

## **Lipids — Pharmacotherapy for LDL Lowering, High Risk Women**

Utilize LDL-C-lowering drug therapy simultaneously with lifestyle therapy in women with CHD to achieve an LDL-C <100 mg/dL (Class I, Level A) and similarly in women with other atherosclerotic cardiovascular disease (CVD) or diabetes mellitus or 10-year absolute risk >20% (Class I, Level B)

A reduction to <70 mg/dL is reasonable in very-high-risk women<sup>4</sup> with CHD and may require an LDL-lowering drug combination (Class IIa, Level B).

## Lipids — Pharmacotherapy for LDL Lowering, Other At-Risk Women

Utilize LDL-C-lowering therapy if LDL-C level is  $\geq$ 130 mg/dL with lifestyle therapy, and there are multiple risk factors and 10-year absolute risk 10% to 20%. (Class I, Level B)

Utilize LDL-C-lowering therapy if LDL-C level is  $\geq$ 160 mg/dL with lifestyle therapy and multiple risk factors even if 10-year absolute risk is <10% (Class I, Level B).

Utilize LDL-C-lowering therapy if LDL  $\geq$ 190 mg/dL regardless of the presence or absence of other risk factors or CVD on lifestyle therapy (Class I, Level B).

# Lipids — Pharmacotherapy for Low HDL or Elevated Non-HDL, High-Risk Women

Utilize niacin<sup>5</sup> or fibrate therapy when HDL-C is low or non–HDL-C is elevated in high-risk women<sup>5</sup> after LDL-C goal is reached (Class IIa, Level B).

# Lipids — Pharmacotherapy for Low HDL or Elevated Non-HDL, Other At-Risk Women

Consider niacin<sup>5</sup> or fibrate therapy when HDL-C is low or non–HDL-C is elevated after LDL-C goal is reached in women with multiple risk factors and a 10-year absolute risk 10% to 20% (Class IIb, Level B).

### **Diabetes Mellitus**

Lifestyle and pharmacotherapy should be used as indicated in women with diabetes (Class I, Level B) to achieve glycosylated hemoglobin ( $HbA_{1C}$ ) <7% if this can be accomplished without significant hypoglycemia (Class I, Level C).

#### **Preventive Drug Interventions**

## Aspirin — High Risk

Aspirin therapy  $(75 \text{ to } 325 \text{ mg/d})^6$  should be used in high-risk<sup>3</sup> women unless contraindicated. (Class I, Level A)

If a high-risk<sup>3</sup> woman is intolerant of aspirin therapy, clopidogrel should be substituted (Class I, Level B).

## Aspirin — Other At-Risk or Healthy Women

In women  $\geq$ 65 years of age, consider aspirin therapy (81 mg daily or 100 mg every other day) if blood pressure is controlled and benefit for ischemic stroke and myocardial infarction (MI) prevention is likely to outweigh risk of gastrointestinal bleeding and hemorrhagic stroke (Class IIa, Level B) and in women <65 years of age when benefit for ischemic stroke prevention is likely to outweigh adverse effects of therapy (Class IIb, Level B).

#### **Beta-Blockers**

Beta-blockers should be used indefinitely in all women after MI, acute coronary syndrome, or left ventricular dysfunction with or without heart failure symptoms, unless contraindicated. (Class I, Level A)

## **ACE inhibitors/ARBs**

ACE inhibitors should be used (unless contraindicated) in women after MI and in those with clinical evidence of heart failure or an LVEF  $\leq$ 40% or with diabetes mellitus (Class I, Level A). In women after MI and in those with clinical evidence of heart failure or an LVEF  $\leq$ 40% or with diabetes mellitus who are intolerant of ACE inhibitors, ARBs should be used instead. (Class I, Level B)

## **Aldosterone Blockade**

Use aldosterone blockade after MI in women who do not have significant renal dysfunction or hyperkalemia who are already receiving therapeutic doses of an ACE inhibitor and beta-blocker, and have LVEF  $\leq$ 40% with symptomatic heart failure (Class I, Level B).

<sup>&</sup>lt;sup>1</sup>Pregnant and lactating women should avoid eating fish potentially high in methylmercury (e.g., shark, swordfish, king mackerel, or tile fish) and should eat up to 12 oz/wk of a variety of fish and shellfish low in mercury and check the Environmental Protection Agency and the US Food and Drug Administration's Web sites for updates and local advisories about safety of local catch.

<sup>2</sup>A drink equivalent is equal to a 12-oz bottle of beer, a 5-oz glass of wine, or a 1.5-oz shot of 80-proof spirit.

<sup>3</sup>Criteria for high risk include established CHD, cerebrovascular disease, peripheral arterial disease, abdominal aortic aneurysm, end-stage or chronic renal disease, diabetes mellitus, and 10-year Framingham risk >20%.

<sup>4</sup>Criteria for very high risk include established CVD plus any of the following: multiple major risk factors, severe and poorly controlled risk factors, diabetes mellitus.

<sup>5</sup>Dietary supplement niacin should not be used as a substitute for prescription niacin.

<sup>6</sup>After percutaneous intervention with stent placement or coronary artery bypass grafting within previous year and in women with noncoronary forms of CVD, use current guidelines for aspirin and clopidogrel.

# Class III Interventions (Not Useful/Effective and May Be Harmful) for CVD or MI Prevention in Women

# **Menopausal Therapy**

Hormone therapy and selective estrogen-receptor modulators (SERMs) should not be used for the primary or secondary prevention of CVD (Class III, Level A).

## **Antioxidant Supplements**

Antioxidant vitamin supplements (e.g., vitamin E, C, and beta carotene) should not be used for the primary or secondary prevention of CVD (Class III, Level A)

## Folic Acid<sup>1</sup>

Folic acid, with or without B6 and B12 supplementation, should not be used for the primary or secondary prevention of CVD (Class III, Level A).

## Aspirin — for MI in Women <65 Years of Age<sup>2</sup>

Routine use of aspirin in healthy women <65 years of age is not recommended to prevent MI (Class III, Level B).

<sup>1</sup>Folic acid supplementation should be used in the childbearing years to prevent neural tube defects.

 $^2$ For recommendation for aspirin to prevent CVD in women  $\geq$ 65 years of age or stroke in women <65 years of age, please see Preventive Drug Interventions section above.

## **Definitions**:

# Strength of Recommendations

Classification:

Class I: Intervention is useful and effective.

Class IIa: Weight of evidence/opinion is in favor of usefulness/efficacy.

**Class IIb**: Usefulness/efficacy is less well established by evidence/opinion.

**Class III**: Intervention is not useful/effective and may be harmful.

#### Level of Evidence

A. Sufficient evidence from multiple randomized trials

- B. Limited evidence from single randomized trial or other nonrandomized studies
- C. Based on expert opinion, case studies, or standard of care

# **CLINICAL ALGORITHM(S)**

A clinical algorithm is provided in the original guideline document for cardiovascular disease (CVD) preventive care in women.

## **EVIDENCE SUPPORTING THE RECOMMENDATIONS**

#### TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

# BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

## **POTENTIAL BENEFITS**

Prevention of chronic atherosclerotic vascular diseases

#### **POTENTIAL HARMS**

- Side effects of medication. For example, aspirin may increase the risk of hemorrhagic stroke and gastrointestinal bleeding.
- Side effects of mercury exposure from eating certain types of fish

## **CONTRAINDICATIONS**

## **CONTRAINDICATIONS**

- Although fish has been associated with a reduced risk of cardiovascular disease (CVD), women of childbearing age, especially pregnant women, should avoid shark, swordfish, king mackerel, and tilefish because the relatively high content of mercury in these fish may impair fetal neurological development.
- Angiotensin-converting enzyme inhibitors and angiotensin receptor blockers are contraindicated in women contemplating pregnancy or in those who are pregnant.

# **QUALIFYING STATEMENTS**

# **QUALIFYING STATEMENTS**

## Limitations

- The expert panel tried to simplify the guidelines as much as possible while attempting to preserve the integrity of the evidence-based process. This required the assumption of a class effect for most therapeutic interventions, and it should be noted that data are limited with regard to gender differences in any potential class effects. Although most agents in a single therapeutic class share similar efficacy in reducing cardiovascular disease (CVD) risk, the safety profiles and costs may vary significantly among agents; healthcare providers should take these factors into consideration as they prescribe pharmacotherapy to prevent CVD.
- The panel also emphasizes that the effectiveness of therapies prescribed in the actual office or hospital setting may vary substantially from the efficacy and safety profiles observed in clinical trials because of wide variations in patient characteristics and adherence to therapy as prescribed. Guideline development has limitations related to the generalizability of results from one population to another. The net clinical impact of an intervention may not be reflected in the scope of CVD outcomes evaluated in these guidelines. Moreover, many studies used to formulate recommendations did not include older women, especially those >80 years of age, in whom CVD and comorbidities are common. Healthcare providers should use clinical judgment about the aggressiveness of preventive interventions in all women, especially older women.

## **IMPLEMENTATION OF THE GUIDELINE**

## **DESCRIPTION OF IMPLEMENTATION STRATEGY**

A suggested algorithm for the prevention of cardiovascular disease (CVD) in women that incorporates the updated guidelines is presented in the original guideline document. Although a comprehensive plan to maximize implementation of the guidelines in various practice settings is beyond the scope of this document, barriers to CVD prevention should be discussed with women. A previous study by the American Health Association (AHA) has documented numerous barriers to heart health in women; chief among them was confusion by mixed messages from the media. Other barriers that healthcare providers can address were as follows: 36% of women did not perceive themselves to be at risk, 25% said their healthcare provider did not say heart health was important, and 1 in 5 said healthcare providers did not clearly explain how they could change their risk status. Physicians have cited lack of insurance coverage as a barrier to assisting their patients with lifestyle changes.

Widespread documentation of lack of adherence to CVD prevention guidelines is available, even among women at high risk of CVD in managed-care settings in the United States in which access and medication coverage are available. Policy makers, healthcare providers, and patients all have roles to play in maximizing adherence to preventive interventions and reducing the burden of CVD. It is also important to recognize that although the causes of CVD are common to all parts of the world, the approaches to its prevention at the societal or individual level will differ among countries for cultural, social, medical, and economic reasons.

## **IMPLEMENTATION TOOLS**

Clinical Algorithm

For information about <u>availability</u>, see the "Availability of Companion Documents" and "Patient Resources" fields below.

# INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

#### **IOM CARE NEED**

Living with Illness Staying Healthy

#### **IOM DOMAIN**

Effectiveness Patient-centeredness

#### **IDENTIFYING INFORMATION AND AVAILABILITY**

# **BIBLIOGRAPHIC SOURCE(S)**

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## **ADAPTATION**

Not applicable: The guideline was not adapted from another source.

# **DATE RELEASED**

2004 Feb (revised 2007 Mar 20)

# **GUIDELINE DEVELOPER(S)**

American Heart Association - Professional Association

# **SOURCE(S) OF FUNDING**

American Heart Association

#### **GUIDELINE COMMITTEE**

Expert Panel/Writing Group for Cardiovascular Disease Prevention in Women

## **COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE**

Expert Panel/Writing Group Members: Lori Mosca, MD, MPH, PhD, Chair; Carole L. Banka, PhD; Emelia J. Benjamin, MD; Kathy Berra, MSN, NP; Cheryl Bushnell, MD; Rowena J. Dolor, MD, MHS; Theodore G. Ganiats, MD; Antoinette S. Gomes, MD; Heather L. Gornik, MD, MHS; Clarissa Gracia, MD, MSCE; Martha Gulati, MD, MS; Constance K. Haan, MD; Debra R. Judelson, MD; Nora Keenan, PhD; Ellie Kelepouris, MD; Erin D. Michos, MD; L. Kristin Newby, MD, MHS; Suzanne Oparil, MD; Pamela Ouyang, MD; Mehmet C. Oz, MD; Diana Petitti, MD, MPH; Vivian W. Pinn, MD; Rita F. Redberg, MD, MSc; Rosalyn Scott, MD; Katherine Sherif, MD; Sidney C. Smith, Jr, MD; George Sopko, MD, MPH; Robin H. Steinhorn, MD; Neil J. Stone, MD; Kathryn A. Taubert, PhD; Barbara A. Todd, MSN, CRNP; Elaine Urbina, MD; Nanette K. Wenger, MD

# FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

The American Heart Association makes every effort to avoid any actual or potential conflicts of interest that may arise as a result of an outside relationship or a personal, professional, or business interest of a member of the writing panel. Specifically, all members of the writing group are required to complete and submit a Disclosure Questionnaire showing all such relationships that might be perceived as real or potential conflicts of interest.

### **Writing Group Disclosures**

Writing Group Member	Employment	Research Grant	Other Research Support	Speakers' Bureau/ Honoraria	Ownership Interest	Consultant/ Advisory Board	0
Lori Mosca	Columbia University	NIH (Pfizer²) (no salary)	Cholestech (in kind) <sup>1</sup> ; Didexus (in kind) <sup>1</sup> ; Lipo Science Inc (in kind) <sup>1</sup>	Abbott <sup>1</sup> Fornier <sup>1</sup> ; Kos <sup>1</sup> ; Merck <sup>1</sup> ; Schering- Plough <sup>1</sup>		Plough <sup>1</sup> ;	Educat grants Colum Univer Choles Fact Founda Organa Pfizer <sup>2</sup> Reliant Unileva Waterf Media <sup>1</sup>
Carole L. Banka	La Jolla Institute for	None	None	None	None	None	None

Writing Group Member	Employment	Research Grant	Other Research Support	Speakers' Bureau/ Honoraria	Ownership Interest	Consultant/ Advisory Board	C
	Molecular Medicine						
Benjamin	University School of Medicine	None	None	None	None	None	None
Kathy Berra	Center for Research & Disease Prevention	None	Kos Pharmaceuticals <sup>1</sup>	None	None	None	None
Bushnell	Duke University Medical Center	None	None	None	None	None	None
	Duke University Medical Center	None	None	None	None	Pfizer <sup>1</sup> ; Wyeth <sup>1</sup>	None
G. Ganiats	California, San Diego	None	None	None	None	Pfizer	None
S. Gomes		None	None	None	None	None	None
Heather L. Gornik	The Cleveland	BMS-Sanofi <sup>1</sup> ; Pfizer <sup>2</sup>	None	None	None	None	None
Clarissa Gracia	University of Pennsylvania	None	None	None	None	None	None
Martha		None	None	None	None	None	None
Constane		None	None	None	None	None	None
	Cardiovascular Medical Group of Southern California	None	None	Biovail <sup>1</sup> ; Kos <sup>1</sup> ; Novartis <sup>1</sup> ; Pfizer <sup>1</sup>	None	Novartis <sup>1</sup> ; Pfizer <sup>1</sup>	Expert
Nora Keenan		None	None	None	None	None	None
Ellie Kelepouris		None	None	None	None	None	None
Erin D.	Johns Hopkins School of	None	None	None	None	None	None

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	Medicine						
Newby	University Medical Center	BMS-Sanofi <sup>2</sup> ; Millennium <sup>2</sup> ; Schering- Plough <sup>2</sup> ; Inverness Medical <sup>1</sup> ; Roche Diagnostics <sup>2</sup>	None	BMS- Sanofi <sup>1</sup> ; Millennium <sup>1</sup>	None	Biosite <sup>1</sup> ; Eli Lilly <sup>1</sup> ; Inverness Medical <sup>1</sup> ; Proctor & Gamble <sup>1</sup> ; Johnson & Johnson <sup>1</sup>	None
Suzanne Oparil	Alabama, Birmingham	Abbott Laboratories <sup>1</sup> ; AstraZeneca <sup>1</sup> ; Aventis <sup>1</sup> ; Biovail <sup>1</sup> ; Boehringer Ingelheim <sup>1</sup> ; Bristol-Myers Squibb <sup>1</sup> ; Forest Laboratories <sup>1</sup> ; Glaxo-Smith Kline <sup>1</sup> ; Novartis <sup>1</sup> ; Merck & Co <sup>1</sup> ; Pfizer <sup>1</sup> ; Sankyo Pharma <sup>1</sup> ; Sanofi- Synthelabo <sup>1</sup> ; Schering- Plough <sup>1</sup>	None	None	None	Bristol-Myers Squibb <sup>1</sup> ; Merck & Co <sup>1</sup> ; Pfizer <sup>1</sup> ; Sanofi <sup>1</sup> ; Novartis <sup>1</sup> ; The Salt Institute <sup>1</sup>	Encysi Pharm BOD <sup>1</sup>
	Johns Hopkins Bayview Medical Center		None	None	None	CV Therapeutics <sup>1</sup>	None
Mehmet C. Oz	Columbia University	None	None	None	None	None	None
Petitti Ad Hoc	Permanente	National Institutes of Health <sup>1</sup>	None	None	None	None	None
	Department of Health and Human Services (NIH)		None	None	None	None	None
Rita F. Redberg			None	Estrasorb <sup>1</sup>	None	CV Therapeutics <sup>1</sup>	None

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	Center						
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Katherine Sherif <sup>3</sup>	Drexel University College of Medicine	Novartis <sup>2</sup>	None	Novartis <sup>1</sup>	None	None	None
Sidney C. Smith, Jr	University of North Carolina, Chapel Hill	None	None	Bayer <sup>1</sup> ; BMS <sup>1</sup> ;Sanofi <sup>1</sup>	None	Eli Lilly <sup>1</sup> ; GlaxoSmith- Kline <sup>1</sup> ; Merck <sup>1</sup> ; Pfizer <sup>1</sup> ; Sanofi- Aventis <sup>1</sup>	AstraZ (DSME
George Sopko	National Heart, Lung, and Blood Institute	None	None	None	None	None	None
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Kathryn A. Taubert	American Heart Association	None	None	None	None	None	None
Barbara A. Todd	Pennsylvania	None	None	None	None	None	None
Elaine Urbina	Cincinnati Children's Hospital	None	None	None	None	None	None
Nanette K. Wenger	Emory University School of Medicine	Eli Lilly <sup>2</sup> ; Astra- Zeneca <sup>1</sup> ; Pfizer <sup>1</sup>	None	Bristol-Myers Squibb <sup>1</sup> ; Eli Lilly <sup>1</sup> ; Merck <sup>1</sup> ; NitroMed <sup>1</sup> ; Novartis <sup>1</sup> ;	None	BMS <sup>1</sup> ; CV Thera- peutics <sup>2</sup> ; Eli Lilly <sup>1</sup> ; GSK <sup>1</sup> ; Kos Pharma- ceuticals <sup>1</sup> ;	None

Writing En Group Member	mployment	Research Grant	Other Research Support	Speakers' Bureau/ Honoraria	Ownership Interest	Consultant/ Advisory Board	0
				Pfizer <sup>1</sup>		Merck <sup>1</sup> ; NitroMed <sup>1</sup> ; Pfizer <sup>1</sup> ; Sanofi- Aventis <sup>1</sup> ; Schering- Plough <sup>1</sup>	

This table represents the relationships of writing group members that may be perceived as actual or reasonably perceived conflicts of interest as reported on the Disclosure Questionnaire, which all members of the writing group are required to complete and submit. A relationship is considered to be "significant" if (1) the person receives \$10,000 or more during any 12-month period, or 5% or more of the person's gross income; or (2) the person owns 5% or more of the voting stock or share of the entity, or owns \$10,000 or more of the fair market value of the entity. A relationship is considered to be "modest" if it is less than "significant" under the preceding definition.

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National Black Women's Health Initiative - Professional Association

National Women's Health Resource Center - Private Nonprofit Organization

Partnership for Gender-Specific Medicine - Professional Association

Preventive Cardiovascular Nurses Association - Medical Specialty Society

<sup>&</sup>lt;sup>1</sup>Modest.

<sup>&</sup>lt;sup>2</sup>Significant.

<sup>&</sup>lt;sup>3</sup>Representation does not imply endorsement by the American College of Physicians.

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The Mended Hearts Inc. - Private Nonprofit Organization
The North American Menopause Society - Private Nonprofit Organization
Women in Thoracic Surgery - Medical Specialty Society
WomenHeart the National Coalition for Women with Heart Disease - Private
Nonprofit Organization

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